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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Chise Mukaidani

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513

7590

05/30/2006

WENDEROTH, LIND &amp; PONACK, L.L.P.

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WASHINGTON, DC 20006-1021

EXAMINER

AEDER, SEAN E

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 05/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/509,096	<b>Applicant(s)</b> MUKAIDANI ET AL.	
	<b>Examiner</b> Sean E. Aeder, Ph.D.	<b>Art Unit</b> 1642	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 March 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                                    |

***Detailed Action***

The Amendments and Remarks filed 3/7/06 in response to the Office Action of 9/7/05 are acknowledged and have been entered.

Claims 1-16 were pending.

Claims 5-16 have been withdrawn.

Claims 1 and 2 have been amended by Applicant.

Claims 1-4 are currently under examination.

The text of those sections of Title 35 U.S.C. code not included in this Office Action can be found in a prior Office Action.

***Claim Status***

It was brought to the attention of the examiner that withdrawn claims 11-16 were inadvertently omitted from the restriction requirement of 9/7/05. Examiner has now grouped the omitted claims as follows:

Claim 11 is part of group 2, drawn to methods of isolating proliferative human hepatocytes with a monoclonal antibody.

Claim 12 is part of group 3, drawn to proliferative human hepatocytes.

Claim 13 is part of group 4, drawn to a method for inducing the differentiation of proliferative human hepatocytes.

Claims 14-15 are part of group 5, drawn to functional human hepatocytes induced to differentiate.

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Claim 16 is part of group 6, drawn to a hybrid artificial liver.

***Foreign Priority***

Examiner acknowledges the claim for foreign priority under 35 U.S.C. 119(a)-(d) or (f) as well as receipt of the certified copies of the foreign priority document (PCT/JP03/03624; 03/25/03).

***Information Disclosure Statement***

An Examiner-initialed copy of the Form PTO 1449 submitted with the IDS of September 27, 2004 is enclosed with this Office Action.

***Response to Arguments***

***35 USC § 112; Enablement Rejection***

Claims 2 and 4 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one of skilled in the art to which it pertains, or to which it is most nearly connected, to make and/or use the invention for the reasons of record in the Office Action of 9/7/05 and the reasons set-forth below.

The Office Action mailed 9/7/05 contained the following text:

The invention appears to employ novel biological materials, specifically the hybridoma K8223 (FERM BP-8334). Since the biological materials are essential to the

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claimed invention they must be obtainable by a repeatable method set forth in the specification or otherwise readily available to the public. If the biological materials are not so obtainable or available, the requirements of 35 U.S.C. 112 may be satisfied by a deposit of the biological materials. The specification does not disclose a repeatable process to obtain the biological materials and it is not apparent if the biological materials are readily available to the public. It is noted that Applicant has deposited the biological materials (paragraph 84), but there is no indication in the specification as to public availability. If the deposit is made under the Budapest Treaty, then an affidavit or declaration by Applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the specific biological materials have been deposited under the Budapest Treaty and that the biological materials will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809, Applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

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- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;
- (d) a test of the viability of the biological material at the time of the deposit will be made (see 37 C.F.R. 1.807); and
- (e) the deposit will be replaced if it should ever become inviable.

Applicant's attention is directed to M.P.E.P. 2400 in general, and specifically to 2411.05, as well as 37 C.F.R. 1.809(d), wherein it is set forth that the "specification shall contain the accession number for the deposit, the date of the deposit, the name and address of the depository, and a description of the deposited material sufficient to specifically identify it and to permit examination." The specification should be amended to include this information, however, Applicant is cautioned to avoid the entry of new matter into the specification by adding any other information.

In response to the Office Action of 9/7/05, Applicant has submitted documents that are allegedly a deposit receipt for the Mouse-Mouse hybridoma K8223 (FERM BP-8334). The Response states that said documents show that the hybridoma was deposited under the terms of the Budapest Treaty. Further, the Response states that access to the deposit will be available during pendency of the patent application making reference to the deposit to one determined by the Director to be entitled thereto and all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon granting of the patent.

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The submitted documents and the arguments found in the Response of 3/7/06 have been carefully considered but are not deemed to be persuasive. Specifically, the deposit receipt submitted in response to this rejection appears to be written in Japanese. This deposit receipt is not in compliance with MPEP 1.52(b), which requires such documents be submitted in the English language or be accompanied by an English translation and a statement that the English translation is accurate.

***35 USC § 112; Written Description Rejection***

Claims 1 and 3 remain rejected under 35 U.S.C. 112, first paragraph, on the basis that the specification lacks written description support for the claimed genus of antibodies that recognize proliferative human hepatocytes for the reasons of record in the Office Action of 9/7/05 and the reasons set-forth below.

Amended claim 1 is drawn to an antibody specifically recognizing proliferative human hepatocytes that exist in a hepatocytes population isolated from an adult human liver and have clonal proliferative ability and differentiation ability to functional hepatocytes, which antibody is produced by a hybridoma cell prepared by using human hepatocytes subcultured for at least four passages as an immunogen. Claim 3 is drawn to a hybridoma cell producing the antibody of claim 1.

The Office Action mailed 9/7/05 contained the following text:

The specification teaches monoclonal antibodies that recognize proliferative human hepatocytes produced by the Mouse-Mouse hybridoma K8223 (paragraph 14).

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However, the claimed genus of monoclonal antibodies that recognize proliferative human hepatocytes is not disclosed in the specification, as the one species disclosed is not adequately representative of the genus.

A description of a genus of monoclonal antibodies that recognize proliferative human hepatocytes may be achieved by means of a recitation of a representative number of monoclonal antibodies that recognize proliferative human hepatocytes, defined by structure, falling within the scope of the genus. However, the instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features of the claimed genus of monoclonal antibodies that recognize proliferative human hepatocytes that would distinguish the claimed monoclonal antibodies that recognize proliferative human hepatocytes from other molecules that do not have the claimed biological properties. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116). As discussed



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above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of monoclonal antibodies that recognize proliferative human hepatocytes, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation.

Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

In response to the Office Action of 9/7/05, Applicant added the phrase “, which antibody is produced by a hybridoma cell prepared by using human hepatocytes subcultured for at least four passages as an immunogen” to claim 1. Further, Applicant points-out that in order to satisfy a written description requirement, a patent specification must describe the claimed invention in sufficient detail so that one skilled in the art can reasonably conclude that the inventor had possession at the time of filing of the subject

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matter which is claimed. Applicant further points-out that this requirement may be satisfied by: (1) reduction to practice, (2) a reduction to drawings/chemical formulas, (3) a disclosure of relevant identifying characteristics, such as structure or other physical and/or chemical properties, to sufficiently describe the claimed invention in full, clear, and concise and exact terms, (4) a disclosure of functional characteristics coupled with a known or disclosed correlation between function and structure, (5) a sufficient description of a representative number of species, or (6) a combination of the above, sufficient to show Applicants were in possession of the invention. Applicants argue that the specification satisfies this requirement and provides full written description support for the genus of claimed antibodies. Applicants argue that a method for obtaining the claimed antibodies is disclosed throughout the specification (pages 10-13, in particular) and that the procedures for producing a monoclonal antibody are conventional and well known in the art. Applicant points-out Example 1 on page 18 of the specification, which discloses the procedure of preparing the antibody of hybridoma cell K8223 (FERM BP-8334). Applicant further states that the claimed antibody is obtained by: (1) use of human hepatocytes subcultured for at least four passages as an immunogen, and (2) selection of hybridoma cells producing an antibody specifically recognizing proliferative human hepatocytes that exist in a hepatocytes population isolated from an adult human liver and have clonal proliferative ability and differentiation ability to functional hepatocytes. Applicants further submit that such disclosure is sufficient written description support for the claimed genus of antibodies and the claimed antibodies could not be obtained unless the procedures (1) and (2) were used. Applicants

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conclude that such a disclosure constitutes a reduction to practice and a sufficient disclosure of relevant identifying characteristics, such a structure or other physical and/or chemical properties, to sufficiently describe the claimed invention in full, clear, concise, and exact terms. Moreover, given such a disclosure, Applicant argue that one of skill in the art could easily produce and test for antibodies with the requisite ability to specifically recognize proliferative hepatocytes that exist in a hepatocytes population isolated from an adult human liver and have clonal proliferative ability and differentiation ability to functional hepatocytes. Applicant further states that one of skill in the art could obtain antibodies of the present invention other than those produced by hybridoma cell Mouse-Mouse hybridoma K8223 (FERM BP-8334) by following the guidance in the disclosure for obtaining and testing antibodies of the requisite properties.

The amendment to the claims and the arguments found in the Response of 3/7/06 have been carefully considered but are not deemed to be persuasive. The amendment to claim 1 attempts to limit the claimed material to a product obtained by a specific process. However, MPEP 2113 states that product-by process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps. Further, "[E]ven though the product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior art was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227, USPQ 964, 966 (Fed. Cir. 1985). Therefore, the phrase "

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which antibody is produced by a hybridoma cell prepared by using human hepatocytes subcultured for at least four passages as an immunogen” does not further define the broad genus of antibodies that recognize proliferative human hepatocytes. Specifically, the newly-recited phrase does not restrict how the claimed antibodies are generated. Although Applicant is clearly in possession of one species of the genus of antibodies that recognize proliferative human hepatocytes (antibodies produced by hybridoma cell Mouse-Mouse hybridoma K8223 (FERM BP-8334)), the claimed genus of monoclonal antibodies that recognize proliferative human hepatocytes is not disclosed in the specification, as the one species disclosed is not adequately representative of the genus. Although a method for obtaining the claimed antibodies is disclosed throughout the specification (pages 10-13, in particular) and procedures for producing a monoclonal antibody are conventional and well known in the art, the specification does not provide sufficient descriptive information, such as definitive structural features of the claimed genus of monoclonal antibodies that recognize proliferative human hepatocytes that would distinguish the claimed monoclonal antibodies that recognize proliferative human hepatocytes from other molecules that do not have the claimed biological properties. It is noted that the genus is extremely broad, as the genus consists of every antibody that would recognize one of numerous vastly-different markers of proliferative human hepatocytes that exist in a hepatocytes population isolated from adult human liver and have clonal proliferative ability and differentiation ability to functional hepatocytes. Since the limitation that the “antibody is produced by a hybridoma cell prepared by using human hepatocytes subcultured for at least four passages as an immunogen”

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holds no patentable weight, one of skill in the art would recognize that antibodies of the claimed genus can be produced by using vastly different methods and can have significant structural differences from antibodies produced by hybridoma cell Mouse-Mouse hybridoma K8223 (FERM BP-8334). For instance, one of skill in the art would recognize that numerous antibodies produced to recognize general markers of cell proliferation, including those antibodies generated without the use of hepatocytes, would specifically recognize proliferative human hepatocytes that exist in a hepatocyte population isolated from an adult human liver and have clonal proliferative ability and differentiation ability to functional hepatocytes. These antibodies include those taught by Hillman et al (Journal Hepatology, 24:385-690, 19965). As indicated by Applicant in the Response of 3/7/06, Hillman never discloses an antibody obtained from a hybridoma cell prepared by using human hepatocytes subcultured for at least four passages as an immunogen. However, the anti-Ki-67 monoclonal antibody taught by Hillman et al specifically recognizes proliferative human hepatocytes that exist in a hepatocytes population isolated from an adult human liver. Further, absent a showing of unobvious differences, the antibody taught by Hillman et al would specifically recognize those proliferative cells what have clonal proliferative ability and differentiation ability to functional hepatocytes. The Office does not have the facilities and resources to provide the factual evidence needed in order to establish that the antibody taught by Hillman et al does not possess the same characteristics of the claimed genus of antibodies. In the absence of evidence to the contrary, the burden is on Applicant to prove that the claimed antibodies are different from that taught by the

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prior art and to establish patentable differences. See *In re Best* 562F .2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2<sup>nd</sup> 1992 (PTO Bd. Pat. App. & Int. 1989). Therefore, since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of monoclonal antibodies that recognize proliferative human hepatocytes, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

***Claim Rejections - 35 USC § 102***

Claims 1 and 3 remain rejected under 35 U.S.C. 102(b), as being anticipated by Hillman et al (1996, Journal of Hepatology, 24:385-390) as evidenced by the Zymed information sheet for anti-Ki-67 monoclonal antibody for the reasons of record in the Office Action of 9/7/05 and the reasons set-forth below.

Amended claim 1 is drawn to an antibody specifically recognizing proliferative human hepatocytes that exist in a hepatocytes population isolated from an adult human liver and have clonal proliferative ability and differentiation ability to functional hepatocytes, which antibody is produced by a hybridoma cell prepared by using human hepatocytes subcultured for at least four passages as an immunogen. Claim 3 is drawn to a hybridoma cell producing the antibody of claim 1.

The Office Action mailed 9/7/05 contained the following text:

Hillan et al. teach an anti-Ki-67 monoclonal antibody that specifically recognizes the Ki-67 antigen in proliferative human hepatocytes (see page 386 and the second full

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paragraph on page 389 and figure 1, in particular). As evidenced by Zymed, the anti-Ki-67 monoclonal antibody is produced by the hybridoma clone MIB 1 (see "clone number" in Zymed product information sheet).

In response to the Office Action of 9/7/05, Applicant added the phrase ", which antibody is produced by a hybridoma cell prepared by using human hepatocytes subcultured for at least four passages as an immunogen" to claim 1. In the Response of 3/7/06, Applicants state that the amended claims call for an antibody that specifically recognizes proliferative human hepatocytes that exist in a hepatocytes population isolated from an adult human liver and clonal proliferative ability and differentiation ability to functional hepatocytes, which is produced by hybridoma cell prepared by using hepatocytes subcultured for at least four passages as an immunogen. Applicants further argue that Hillman never discloses an antibody obtained from a hybridoma cell prepared by using human hepatocytes subcultured for at least four passages as an immunogen. Further, Applicants allege that Hillman fails to disclose or suggest that an antibody that recognizes hepatocytes having clonal proliferative ability and differentiation ability to functional hepatocytes.

As noted above, MPEP 2113 states that product-by process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps. Further, "[E]ven though the product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-



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by-process claim is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior art was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227, USPQ 964, 966 (Fed. Cir. 1985). Therefore, the phrase “, which antibody is produced by a hybridoma cell prepared by using human hepatocytes subcultured for at least four passages as an immunogen” does not restrict the claimed antibodies to those produced by the newly-recited process. Hillan et al. teach an anti-Ki-67 monoclonal antibody that specifically recognizes the Ki-67 antigen in proliferative human hepatocytes (see page 386 and the second full paragraph on page 389 and figure 1, in particular). As evidenced by Zymed, the anti-Ki-67 monoclonal antibody is produced by the hybridoma clone MIB 1 (see “clone number” in Zymed product information sheet). Further, absent a showing of unobvious differences, the antibody taught by Hillman et al would specifically recognize those proliferative cells that have clonal proliferative ability and differentiation ability to functional hepatocytes. The Office does not have the facilities and resources to provide the factual evidence needed in order to establish that the antibody taught by Hillman et al does not possess the same characteristics of the claimed genus of antibodies. In the absence of evidence to the contrary, the burden is on Applicant to prove that the claimed antibodies are different from that taught by the prior art and to establish patentable differences. See *In re Best* 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2<sup>nd</sup> 1992 (PTO Bd. Pat. App. & Int. 1989).

### ***Summary***

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No claim is allowed. Claims 2 and 4 are rejected under 35 U.S.C. 112, first paragraph, but free of the prior art teaching the Mouse-Mouse hybridoma K8223 (FERM BP-8334) and antibodies produced by said hybridoma. The closest prior art for claims 2 and 4 is taught by Hillman et al (1996, Journal of Hepatology, 24:385-390); however, this reference does not teach or suggest the Mouse-Mouse hybridoma K8223 (FERM BP-8334) and antibodies produced by said hybridoma.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. ' 1.136(a). A shortened statutory period for response to this Final Action is set to expire three months from the date of this action. In the event a first response is filed within two months of the mailing date of this Final Action and the advisory action is not mailed until after the end of the three-month shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. '1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than six months from the date of this Final Action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SEA

  
JEFFREY SIEW  
SUPERVISORY PATENT EXAMINER